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09/28/2009

EXAMINER

MAEWALL, SNIGDHA

ART UNIT

PAPER NUMBER

1612

NOTIFICATION DATE

DELIVERY MODE

09/28/2009

ELECTRONIC

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Notice of the Office communication was sent electronically on above-indicated "Notification Date" to the following e-mail address(es):

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| | | | |
|------------------------------|--------------------------------------|---|--|
| Office Action Summary | Application No. 10/509,949 | Applicant(s) PEREZ-CAMARGO ET AL. | |
| | Examiner Snigdha Maewall | Art Unit 1612 | |

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 05 May 2009.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 29-32, 34-40, 42-46 and 48-56 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 29-32, 34-40, 42-46 and 48-56 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | Paper No(s)/Mail Date. _____ |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08) | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

Summary

1. Receipt of Applicant's arguments/remarks and amended claims all filed on 05/05/09 is acknowledged.

Claims 1-28, 33, 41 and 47 have been cancelled, claims 30, 38, 40 and 46 have been amended.

Claims pending in the prosecution are claims **29-32, 34-40, 42-46 and 48-56**.

The 35 USC 112.1 rejections have been made in view of Applicant's amendments to claims.

New rejections have been made in this Office Action, which are not necessitated by claim amendments, therefore this action is Non-Final.

Claim Rejections - 35 USC § 112

2. The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

3. Claims 29-32, 34-40, 42-46 and 48-56 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

In claim 29 and 39, it is not clear if pet animal lacks pancreatic function, or is healthy or condition of pet animal is not clear and thus the claim is indefinite. Applicants have not described in claim 1 any specific pancreatic function promoter, liver function promoter or intestinal mucosa function promoter, it is not clear how an intestinal mucosa function promoter or pancreatic function promoter will increase lipid absorption and further improve physical and mental activity, and aging or increase lipid fraction. The correlation between an assimilation of lipid versus intestinal mucosa function is not clear and thus the claim is indefinite. It is not clear what kind of pancreatic extract is the applicant referring to. Claim 44 recites the limitation "agent and carrier", Claim 50 recites a limitation "whey protein, the metes and bounds of claims are not defined. Independent claims 29 and 39 recite the limitation "pancreatic extract", it is not clear which component is the applicant referring to, or what kind of extract is utilized, No specific recitation of structure has been recited, the claims are thus indefinite.

Claims as recited do not specify if the lipid assimilation is due to pancreatic function promoter, liver function promoter or intestinal function promoter. The claims are thus indefinite. The claims also do not specify any correlation between each and every pancreatic, liver and intestinal function promoter with each and every benefit claimed. It is not clear how buffer, a prebiotic or an intestinal promoter such as carrier will be effective in lipid assimilation. It is also not clear how an alkalinizer or acidifier will increase lipid assimilation. The claims as recited do not link any benefit with any effect individually.

Claim 34 recites the limitation “restored functionality of the digestive system” which makes the claim indefinite because it is not clear which functionality of which system the applicant is referring to. Claim 48 provides the limitation “fatty acid profile selected to improve lipid absorption”. The claim depends from claim 44 which has a fat transportation aid, agent and carrier. It is not clear how an agent or carrier without any specifics listed can improve fatty acid lipid absorption. It is also not clear how an agent or carrier be intestinal mucosa function promoter in claim 44.

In claim 51, it is not clear what Applicant defines as general health aspects. In claim 52, it is not clear what applicant means by optimized fecal volume, enhanced gut detoxification. The claim is thus indefinite. Claim 43 recite the limitation that liver function promoter increases glutathione which makes the claim indefinite as it is not clear how liver function promoters such as taurine, emulsifiers, vitamins, minerals and glutathione itself increase glutathione. In claim 45, it is not clear how any or every protease has capacity to promote the function of lipoproteins, the metes and bounds of protease which promotes lipoproteins is not defined which makes the claim indefinite.

Examiner suggests reciting specific components associated with specific benefits. Appropriate corrections are requested.

Response to Arguments

4. Applicant's arguments filed 05/05/09 have been fully considered but they are not persuasive.

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Applicant argues that each claim is distinct and requires specific promoters and contends that one having ordinary skill in the art would understand the metes and bounds of claims given that claim 29 recites a one step method and claim 39 recites a regimen comprising a two part dietary component.

Applicant's arguments are not clear because there is no nexus provided how various components claimed help in treating various conditions of pet once the food comprising the components are administered. The argument that the improvement in conditions occurs only due to one step that is by administering the food comprising the claimed components still does not provide any scientific correlation between various benefits claimed versus the claimed components. It is to be noted that while claims are interpreted in light of specification/disclosure, the limitations are not imported from specification.

Claim Rejections - 35 USC § 102

5. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

6. Claims 39-40, 42, 44, 46, 51-54 are rejected under 35 U.S.C. 102(b) as being anticipated by US 4,759,933 ('933).

'933 teaches a product comprising fish meat mixed with an oil and further consisting of proteolytic enzymes and/or protein digesting micro-organisms (abstract, claims 10, 13 and 16). '933 teaches mixtures of **pancreatin (a proteolytic enzyme**

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and reads on pancreatic extract) and lactobacilli (a protein digesting micro-organisms, or instant spec teaches this is a probiotic pg. 12) and oils such as fish oil (col. 2, lines 45, col. 3, lines 1 and 10-30; Examples 26 and 29). It is to be noted that fish oil comprises omega 3 fatty acids.

'933 teaches adding egg or soybean (instant spec teaches these are emulsifiers and therefore liver function promoters pg. 13) (col. 2, lines 28 and 40-42). '933 teach papain (col. 2, line 67) (a protease according to the instant spec pg. 10). Since the prior art teaches a composition comprising the claimed components, the property of the composition for being utilized for better physical appearance is associated with the chemical composition of the nutritional product. Additionally, since the claims are drawn to composition, various benefits claimed are intended use of the composition which is not given patentable weight to the claims drawn to composition.

7. Claims 29, 31-32, 34-39, 42-45 and 48-56 are rejected under 35 U.S.C. 102(b) as being anticipated by USP Howley et al. (USP 4,804,549).

Howley teaches Dog food palatability enhancer, see title. Howley teaches a pet food with better palatability which enhances the acceptability of pet foods. Howley teaches in example 1 lipase, protease, whole sweet whey, soy concentrate. Claim 14 teaches soy, whey, egg and protease. Pancreatic lipase (a pancreatic function promoter as claimed) is the preferred enzyme, see column 6, lines 11-12. The composition which is nutritionally balanced comprising sufficient protein, carbohydrates, fat, vitamins (a liver function promoter as claimed) and minerals is applied to the surface of food

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product to improve palatability, see column 2, lines 25-30. Since the pet food has nutritionally balanced components, the pet food would increase outward appearance of the pet once administered.

Claim Rejections - 35 USC § 103

8. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

9. Claims 29-32, 34-40, 42-46 and 48-56 are rejected under 35 U.S.C. 103(a) as being unpatentable over US 6,210,718 ('718) in view of Steiner et al (USP 6,855,506).

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'718 teaches a nutrient composition comprising proteins, fats such as fish oil (col. 7, lines 42), an enzyme such as **lipase** as a digestion aid (col. 8, lines 19-26), **probiotics** to benefit the gastrointestinal flora such as lactobacillis, etc (col. 8, lines 38-62).

'718 teaches that the enzymes, microorganisms, etc promote enhance digestive activity, **nutrient absorption or maturation of the gastrointestinal system** as a whole (col. 11, lines 55-62). '718 teaches adding **vitamins and minerals** such as **vitamin E** (instant spec teaches that this is a glutathione promoter) (col. 8, lines 28-38). '718 teach that the proteins can be from **whey** (col. 7, line 24).

'718 does not teach a single embodiment with all these components, but does teach that the components form a nutrient formulation for **poultry and animals**.

The reference teaches lipase but the reference does not teach pancreatic extract (which is taught to be lipase in instant specification).

Steiner et al. teach utilization of pancreatic lipase as an enzyme essential for the absorption of dietary triglycerides fatty acids, see column 2, lines 1-2.

It would have been obvious to one of ordinary skill in the art at the time the invention was made to utilize pancreatic extract lipase in the teachings of '718. One of ordinary skill in the art would have been motivated to do so because secondary reference teaches that pancreatic lipase is essential for the absorption of dietary triglycerides fatty acids. Based on the teachings of the prior art, one of ordinary skill in the art would have substituted one digestion aid lipase with pancreatic lipase as the prior art teaches that pancreatic lipase is essential for the absorption of dietary long chain fatty acids and thus facilitating digestion of dietary food.

10. Claims 29-32, 34-35, 37-40, 42-46 and 48-56 are rejected under 35 U.S.C. 103(a) as being unpatentable over US 6,471,999 ('999) in view of Steiner et al (USP 6,855,506).

'999 teach a pet milk powder as nutritional milk that result in reduced gastrointestinal intolerance (abstract). '999 teaches that the milk powder when administered in an effective amount with the nutritional composition reduces **gastrointestinal intolerance** and that it may further comprise one or more lipid source,

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protein source, vitamins and minerals, and teaches a specific aspect which comprises lactose (of micro-organism origin), **lactase** (an enzyme), taurine, arginine and choline (claims 1-9; col. 2, lines 9-lines 26).

'999 teach **omega fatty acids** such as soybean and rapeseed oil and in Examples 1-2 (col. 3, lines 15-20). '999 teaches chicory fibers, inulin, fructooligosaccharides with the probiotic micro-organism have a symbiotic relationship for promoting beneficial effects (col. 4, lines 9-14) (according to the limitations of claim 48). '999 teach including an alkali in the milk-based powder, which slows the pH drop in the gastrointestinal tract (col. 2, lines 53-55). '999 teaches that a protein source of whey protein and further supplemented with taurine and a probiotic micro-organism which beneficially effects the host by improving its **intestinal microbial balance**, such as lactic acid (col. 3, lines 25-40). '999 teaches that the amount of nutritional composition is to be fed to a mammal each day depends of factors such as age, type of mammal (dogs and cats), and other nutritional sources (col. 4, lines 25-36).

Examples 1 and 2 teach mixing the milk powder, galactosidase (lactase amino, an enzyme), vitamins, minerals, and soybean oil, and adding water to provide nutritional supplement to **dogs and puppies or cats**.

'999 teaches that a protein source of **whey protein** and further supplemented with taurine and a probiotic micro-organism which beneficially effects the host by improving its intestinal microbial balance, such as lactic acid (col. 3, lines 25-40) (according to the limitations of claims 55 and 58-60).

'999 do not teach pancreatic extract.

Steiner et al. teach utilization of pancreatic lipase as an enzyme essential for the absorption of dietary long chain triglycerides fatty acids. (See column 2, lines, 1-2).

It would have been obvious to one of ordinary skill in the art at the time the invention was made to utilize pancreatic extract lipase in the teachings of '999. One of ordinary skill in the art would have been motivated to do so because secondary reference teaches that pancreatic lipase is essential for the absorption of dietary triglycerides fatty acids. Since '999 is directed to nutritional product which reduces gastrointestinal intolerances, one would have been motivated to add pancreatic extract lipase in order help in absorption of long chain fatty acids during digestion process as taught by secondary references.

From the teachings of the reference, it is apparent that one of ordinary skill in the art would have had a reasonable expectation of success in producing the claimed invention. Therefore, the invention as a whole would have been prima facie obvious to one of ordinary skill in the art at the time the invention was made, as evidenced by the references, especially in the absence of evidence to the contrary.

11. Claims 31 and 42-43 are rejected 35 U.S.C. 103(a) as being unpatentable over Couzy et al. (US Patent No. 6,471,999) in view of Steiner et al (USP 6,855,506) as set forth above and further in view of US 5,290,571 ('571) and USP 5,451,412 ('412).

The teachings of the references discussed above do not teach whey protein as glutathione promoter. Couzy teaches whey protein but does not teach the use of whey

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protein in producing glutathione (a liver function promoter).

'571 or '412 teach glutathione.'571 or '412 teach a composition of whey protein concentrate (abstract).

'571 teach that a suitable source of whey protein is known by the trademark PROMOD, which contains whey protein and soy lecithin (col. 5, lines 34-41).

Soy lecithin is taught by applicant in instant Example 2 to be an appropriate liver function promoter. '571 teach that glutathione GSH promotion is a major function of the whey protein concentrate (w.p.c.) (col. 1, lines 30-37). '571 teaches the production of glutathione in the spleen, heart, liver is greater in mice fed with w.p.c, than mice fed with egg white protein (col. 4, lines 39-46). '571 teaches that the object of the invention is to provide **a method for increasing the concentration level of glutathione in the organs and enhancing resistance to bacterial infection of mammals through the use of w.p.c.** via oral administration (col. 10, lines 46-57). '571 also teach inclusion of vitamins B1 and B2 with w.p.c. (claim 1-3, col. 11, lines 55-57).

'412 claims 1 and 2 teach compositions containing whey protein concentrate that promote glutathione as nutritional supplements to animals.

It would have been obvious to one of ordinary skill in the art at the time the invention was made to utilize whey protein in the composition of Couzy ('999) for producing glutathione because '412 teaches whey protein concentrate that promote glutathione in nutritional supplements to animals and '512 teaches that glutathione helps in enhancing resistance to bacterial infection of mammals.

Response to Arguments

12. Applicant's arguments with respect to claims 29-32, 34-40, 42-46 and 48-56 have been considered but are moot in view of the new ground(s) of rejection.

13. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Snigdha Maewall whose telephone number is (571)-272-6197. The examiner can normally be reached on Monday to Friday; 8:30 a.m. to 5:00 p.m. EST.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Frederick Krass can be reached on (571) 272-0580. The fax phone number for the organization where this application or proceeding is assigned is 571-273-0580.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only.

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Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/Snigdha Maewall/

Examiner, Art Unit 1612

/Gollamudi S Kishore/

Primary Examiner, Art Unit 1612